

IN THE UNITED STATES DISTRICT COURT
DISTRICT OF NORTH DAKOTA
WESTERN DIVISION

ALLEN BAUMGARTNER

Plaintiff,

v.

ZIMMER BIOMET HOLDINGS, INC. f/k/a
ZIMMER HOLDINGS, INC.;
ZIMMER, INC.; ZIMMER SURGICAL, INC.
f/k/a ZIMMER ORTHOPAEDIC SURGICAL
PRODUCTS, INC.; and ZIMMER GmbH,

Defendants.

Case No.: 1:16-cv-356

COMPLAINT

DEMAND FOR JURY TRIAL

Plaintiff Allen Baumgartner alleges as follows based on information and belief:

I. PARTIES

A. Plaintiff

1. Plaintiff Allen Baumgartner ("Plaintiff") is currently a resident of Burleigh County, North Dakota.

2. Plaintiff underwent a hip replacement surgery during which he received a Zimmer® MMC® Acetabular Component ("MMC Cup") in conjunction with Zimmer Metasul femoral head and head adapter, and a Zimmer femoral stem (hereafter, the MMC Cup, the femoral head and head adapter, and the femoral stem will be collectively referred to as "the Device").

3. The Device failed, causing Plaintiff severe injuries including the need for a surgery to remove and replace the Device.

B. Defendants

4. Defendant Zimmer Biomet Holdings, Inc. f/k/a Zimmer Holdings, Inc. is a Delaware corporation with its principal place of business at 345 East Main Street, Warsaw, Indiana, 46580-2746. At all relevant times, Zimmer Biomet Holdings, Inc. f/k/a Zimmer Holdings, Inc. directly and/or through its parent, affiliate and subsidiary companies, designed, manufactured, marketed, supplied and/or sold to distributors, physicians, hospitals, patients and/or medical practitioners hip implant devices, including MMC Cups and other components such as those used in the Device, to be surgically implanted in patients throughout the United States, including in the State of North Dakota.

5. Defendant Zimmer, Inc. is a Delaware corporation with its principal place of business at 1800 West Center Street, Warsaw, Indiana, 46581-0708. Defendant Zimmer, Inc. is a wholly owned subsidiary of Defendant Zimmer Biomet Holdings, Inc. f/k/a Zimmer Holdings, Inc. At all relevant times, Zimmer, Inc. was a wholly owned domestic subsidiary of Defendant Zimmer Biomet Holdings, Inc. f/k/a Zimmer Holdings, Inc. At all relevant times, Defendant Zimmer, Inc., directly and/or through its parent, affiliate and subsidiary companies, designed, manufactured, marketed, supplied and/or sold to distributors, physicians, hospitals, patients and/or medical practitioners hip implant devices, including MMC Cups and other components such as those used in the Device, to be surgically implanted in patients throughout the United States, including in the State of North Dakota.

6. Defendant Zimmer Surgical, Inc. f/k/a Zimmer Orthopaedic Surgical Products, Inc. is a Delaware corporation with its principal place of business at 200 West Ohio Ave, Dover, OH 44622-9642. Defendant Zimmer Surgical, Inc. f/k/a Zimmer Orthopaedic Surgical Products, Inc. is a wholly owned subsidiary of Defendant Zimmer Biomet Holdings, Inc. f/k/a Zimmer Holdings, Inc. At all relevant times, Zimmer Surgical, Inc. f/k/a Zimmer Orthopaedic Surgical

Products, Inc. was a wholly owned domestic subsidiary of Defendant Zimmer Biomet Holdings, Inc. f/k/a Zimmer Holdings, Inc. At all relevant times, Defendant Zimmer Surgical, Inc. fka Zimmer Orthopaedic Surgical Products, Inc., directly and/or through its parent, affiliate and subsidiary companies, designed, manufactured, marketed, supplied and/or sold to distributors, physicians, hospitals, patients and/or medical practitioners hip implant devices, including MMC Cups and other components such as those used in the Device, to be surgically implanted in patients throughout the United States, including in the State of North Dakota.

7. Defendant Zimmer GmbH is a Swiss corporation with its principle place of business at Sulzer-Allee 8 CH-8404 Winterthur, Switzerland. At all relevant times, Zimmer GmbH was a wholly owned foreign subsidiary of Defendant Zimmer Biomet Holdings, Inc. f/k/a Zimmer Holdings, Inc. Defendant Zimmer GmbH is a wholly owned subsidiary of Defendant Zimmer Biomet Holdings, Inc. f/k/a Zimmer Holdings, Inc. Defendant Zimmer GmbH, directly and/or through its parent, affiliate and subsidiary companies, designed, manufactured, marketed, supplied and/or sold to distributors, physicians, hospitals, patients and/or medical practitioners hip implant devices, including MMC Cups and other components such as those used in the Device, to be surgically implanted in patients throughout the United States, including in the State of North Dakota.

8. Hereafter, Defendants Zimmer Biomet Holdings, Inc. f/k/a Zimmer Holdings, Inc., Zimmer, Inc., Zimmer Surgical, Inc. f/k/a Zimmer Orthopaedic Surgical Products, Inc., and Zimmer GmbH will be collectively referred to as “Defendants.”

9. At all relevant times and with respect to all acts and omissions set forth in this Complaint, Defendants were the agents, divisions, subsidiaries, and/or partners of each other, and Defendants committed, approved, ratified, and/or acquiesced in, the acts and omissions alleged in this Complaint. At all relevant times and with respect to all acts and omissions set

forth in this Complaint, each of the Defendants, including their directors and officers, acted on behalf of each other Defendant and within the scope of their authority to so act. At all relevant times and with respect to all acts and omissions set forth in this Complaint, Defendants possessed a unity of interest amongst them and exercised control over their respective subsidiaries and affiliates. As such, each of the Defendants is individually, as well as jointly and severally, liable to Plaintiff for Plaintiff's injuries, losses and damages.

II. JURISDICTION AND VENUE

10. The Court has subject matter jurisdiction pursuant to 28 U.S.C. § 1332 (a) because Plaintiff and Defendants are citizens of different States and the amount in controversy exceeds \$75,000.00 exclusive of interest and costs.

11. Venue is proper in the United States District Court, District Court of North Dakota, Western Division as the "judicial district in which a substantial part of the events or omissions giving rise to the claim occurred." 28 U.S.C. § 1391 (b)(2).

12. Plaintiff received the MMC Cup in his right hip at a hospital located in Burleigh County, North Dakota. Plaintiff's surgeon then maintained an office in Burleigh County, North Dakota. At the time of that surgery, Plaintiff was a resident of Burleigh County, North Dakota.

13. At all relevant times, Defendants were present and transacted, solicited and conducted substantial business in the State of North Dakota, directly through their employees, agents and/or sales representatives, and/or through their parent, affiliate and subsidiary companies, and derived substantial revenue from such business.

14. At all relevant times, Defendants expected or should have expected that their acts and omissions would have consequences within the United States and the State of North Dakota.

III. DISCOVERY RULE, FRAUDULENT CONCEALMENT AND TOLLING

15. The nature of Plaintiff's injuries and damages, and their relationship to the Device, was not discovered, and through reasonable care and due diligence could not have been discovered, by Plaintiff, until a time less than six years before the filing of this Complaint.

16. Defendants are estopped from asserting a statute of limitations defense because Defendants fraudulently concealed from Plaintiff the nature of Plaintiff's injuries and the connection between the injury and Defendants' tortious conduct.

17. Defendants have agreed to toll the statute of limitations applicable to Plaintiff's claims from May 20, 2016 through October 18, 2016.

IV. FACTUAL ALLEGATIONS

Hip Replacement Devices - Generally

18. The human hip joint consists of two parts: a ball and a socket. A portion of the pelvic bone forms a cup-shaped socket. The ball at the top of the thigh, femoral, bone fits into that socket. The ball is surrounded with cartilage which, in a healthy hip joint, allows the ball to move smoothly within the socket. Conditions such as osteoarthritis and avascular necrosis can cause degeneration of the hip joint such that hip replacement is required. A hip implant is

designed to replicate the human anatomy. Total hip replacement surgery involves implanting an artificial ball and socket, or cup, into the patient.

19. The artificial hip implantation process is called total hip arthroplasty (“THA”), or total hip replacement. It requires a surgeon to insert a metal cup with a smooth internal surface or lining into the patient’s diseased natural pelvic socket. The surgeon also must cut off the diseased or degenerated part of the femoral bone including the entirety of the ball and fix a metal stem into the remaining femoral bone. Then, the surgeon must fix the artificial ball onto the stem (often through an adaptor). Finally, the surgeon must place the ball securely into the artificial metal cup, where it should move easily, without friction or pain to the patient. The smooth internal surface of the cup serves the same purpose as natural cartilage. It allows for the smooth movement of the ball within the socket.

20. The artificial cup can be fixed to the natural pelvic socket using special cement and/or screws. But, many cups are designed to be fixed to the pelvic bone through natural bone growth. Those cups have a porous, rough surface on the outside of the cup. That surface is impacted into specially prepared natural pelvic socket bone, and the bone grows into the porous spaces of the coating, creating a more natural mode of fixation.

The MMC Cup – History and Specifications

21. On or about April 8, 2009, Defendants submitted a section 510(k) Premarket Notification of Intent (K091003) to the United States Federal Drug Administration (“FDA”) to manufacture and market the MMC Cup in the United States. However, no clinical studies were conducted in connection with the submission of the application for the MMC Cup. Rather, Defendants represented the MMC Cup to the FDA as being “substantially equivalent” to similar

devices already on the market. The FDA did not review the effectiveness or the safety of the MMC Cup, and made no determination in that regard, at any time.

22. The MMC Cup is a monoblock (constructed of a single piece of material) cup made of a cobalt chromium (CoCr) alloy and is designed for use in THA in combination with Defendants' Metasul Metal-on-Metal Tribological Solution LDH (Large Diameter Heads).

23. The MMC Cup is a forged design utilizing a Protasul-21 WF wrought forged cobalt chrome alloy with high carbon content. The carbides of that alloy are up to 40x smaller than those present in cast cobalt chrome alloys. Smaller carbides lead to a significant decrease in the roughness of the surface of the forged alloy.

24. The outer surface of the MMC Cup features a Porolock (Ti-VPS) coating. Ti-VPS stands for vacuum plasma sprayed (VPS) titanium (Ti). That coating is intended to achieve the fixation of the MMC Cup to the pelvic bone.

The Defects of the MMC Cup – Lack of Fixation to the Bone

25. The outer surface of the MMC Cup is defective in design and manufacture. The MMC Cup is designed to be impacted into the pelvic bone to create primary fixation through press fit. However, the design of the cup includes protruding fins on the outer surface that make installation of the cup with the requisite press fit unreasonably difficult. In addition, the structure and/or the size of the pores on the outer surface of the MMC Cup are not adequate for the bone to attach to, and to grow into, the surface of the cup. As a result, the MMC Cup is unreasonably difficult to implant in a way that achieves primary fixation and subsequent bone growth and secondary fixation to the pelvic bone. Rather, a patient receiving an MMC Cup is exposed to an unreasonable risk of the cup remaining fully or excessively unattached to the pelvic bone, which

can lead to movement and shifting of the cup within the pelvic bone. Such lack of fixation, movement and shifting, in turn, can lead to the release of cobalt and chromium ions into the hip and the rest of the body, and result in severe injuries and damage to the hip including pain, damage to the hip tissues and bone, and the need for a surgery to remove and replace the defective MMC Cup and other components of the Device.

26. Defendants failed to bring to light the deficiencies of the MMC Cup and the Device because they chose not to conduct animal, clinical or other studies designed to test the effectiveness and safety of the MMC Cup and the Device, including of the outer surface of the MMC Cup and its ability to achieve fixation to the pelvic bone. By doing so, Defendants failed to conform to the applicable governmental and/or industry standards, subjecting patients to an unreasonable risk of injury.

27. Defendants failed to bring to light the deficiencies in the design and manufacture of the MMC Cup and the Device due to poor and inadequate quality assurance procedures, including the failure to implement appropriate physical, manual, x-ray, microscopic and other inspections of the product. Defendants failed to implement or utilize adequate safeguards, tests, inspections, monitoring and quality assessments to ensure safety of the MMC Cup and the Device. At the time the devices were manufactured and sold to patients, the devices were defectively designed and manufactured and unreasonably dangerous, and did not conform to the applicable governmental and/or industry standards, subjecting patients to an unreasonable risk of injury.

28. Defendants knew or should have known of the said defects in the design and manufacture of the outer surface of the MMC Cup because both the forged cobalt chrome alloy and the Ti-VPS coating of the MMC Cup are same as in another defective product made by Defendants, the Zimmer Durom cup (“Durom Cup”).

The Durom Cup – the Defects, the Deception, and the Lack of Concern for Patients’ Safety

29. Just like the MMC Cup, the Durom Cup was designed for use in combination with Zimmer’s Metasul Metal-on-Metal Tribological Solution LDH (Large Diameter Heads) for THA. Just like the MMC Cup, the Durom Cup was a forged design utilizing a Protasul-21 WF wrought forged cobalt chrome alloy with high carbon content, and its outer surface featured a Porolock (Ti-VPS) coating.

30. Defendants began to aggressively market and distribute the Durom Cup in the United States in or around March 2006.

31. Relying upon Defendants’ representations, physicians began broadly using the Durom Cup instead of other models. But, reports of Durom Cup failures soon followed.

32. By the time Plaintiff received his MMC Cup, the failure rate for the Durom Cup was estimated at upwards of 24% (twenty-four percent) when analyzing patients over a four-year period (2006-2010).

33. Lawrence Dorr, M.D., a world-renowned orthopedic surgeon and a Defendants’ consultant, and a team of doctors at The Arthritis Institute at Good Samaritan Hospital in Los Angeles, California, have published the results of their study comparing one hundred and eighty patients who had the large-diameter (44- to 50-mm) Durom Cup and fifty-four patients who had a small-diameter (28-mm Metasul®) articulation implanted between May 2006 and November 2007. The total number of clinical failures was forty-one of one hundred and eighty patients (23%). Twenty-eight of one hundred and fifty-one patients had radiographic impending failure at final follow-up (18.5%). All post-revision surgery retrieved cups were examined in detail and had no evidence of bone on the fixation surface.

34. Since at least 2007, surgeons implanting the Durom Cup complained to Defendants that the device was failing in their patients, many of whom had to undergo painful, invasive and expensive revision surgeries.

35. One of these surgeons was Dr. Dorr, who warned Defendants in 2007 of the high rate of Durom Cup failures. At the time Dr. Dorr warned Defendants of the high rate of failures, he was a veteran of thousands of hip replacement surgeries.

36. In particular, Dr. Dorr informed Defendants that x-rays showed that the Durom Cup was failing because it was separating or loosening from the bone, rather than fusing to it, causing patients crippling pain while the metal cup moved around the hip socket and rubbed against the bone.

37. Defendants ignored Dr. Dorr's warnings and continued to sell the Durom Cup.

38. In April 2008, Dr. Dorr publicly warned other orthopedists about the cup failures his patients were experiencing and urged Defendants to stop selling the Durom Cup.

39. On April 22, 2008, Dr. Dorr wrote the following memorandum to his colleagues at the American Association of Hip and Knee Surgeons:

MEMO

DATE: 4/22/08

TO: American Association of Hip and Knee Surgeons

FROM: Larry Dorr, M.D.

RE: This NOTICE is to inform you that we have had ten revisions in 165 hips and have four more that need to be revised using the Durom cup (Zimmer, Inc).

*This **failure rate** has occurred within the first two years. In the first year the x-rays looked perfect. We have revised four that did not have any radiolucent lines or migration (and John Moreland revised one). These early cups fooled us, but the **symptoms were so classic for loose implant** that we operated on the patients. When we hit on the edge of the cup **it would just pop free**. As time goes by the cups begin developing radiolucent lines. We now have one cup at two years that has actually migrated a short distance. It has tilted into varus. **We do not believe***

the fixation surface is good on these cups. Also there is a circular cutting surface on the periphery of the cup that we believe prevents the cup from fully seating. We stopped using the cup after the first revisions.

We have notified Zimmer. The FDA has been notified and we will notify them of our continued revisions. The company does not believe it should pull the cup from the market so I am notifying all of my colleagues of our failure rate with this cup. I went through a similar scenario with the Sulzer cup failures where I was the only one experiencing revisions at the beginning and basically it was assumed that it was our technique. I can assure you that this goes beyond technique. I learned my lesson in not informing everyone about this magnitude of failures with the Sulzer cup problem, so it is my obligation to do so with this cup.

(emphasis in original).

40. After informing colleagues about his experience with the Durom Cup, Dr. Dorr heard from several other doctors who reported similar problems. According to Dr. Dorr and other physicians, x-rays of patients who received defective Durom Cups showed that the socket was separating from bone, rather than fusing with it.

41. Despite Dr. Dorr's memorandum, Defendants again ignored the warnings and continued to sell the Durom Cup.

42. In late May 2008, Defendants finally informed surgeons that they were investigating Dr. Dorr's complaint but did not suspend sales as Dr. Dorr had recommended. While Defendants investigated the complaints, roughly 1300 more patients were implanted with the Durom Cup in the United States.

43. Defendants responded by defending the Durom Cup and blaming the doctors' implantation techniques. Defendants later attributed failures of the Durom Cup to a discrepancy in doctors' techniques in performing THA surgeries. Defendants contended (and still contend) that the technology and design parameters of the Durom Cup demand a surgical technique with "high precision and specificity compared to more common and familiar hip arthroplasty surgical techniques practiced in the L .S." Therefore, according to Defendants, the Durom Cup requires

additional training in implantation technique and cup placement for many surgeons who use the device and who may otherwise may be experts in THA.

44. Defendants' investigation included clinical investigation and interviews with surgeons at eight high volume clinical sites in the United States and four in Europe. According to an article published in the New York Times, on Friday June 18, 2010, entitled, "*Surgeon vs. Knee Maker: Who's Rejecting Whom?*," "two doctors who provided Zimmer with supportive data in 2008 said the hip started failing soon afterward in their patients, too. One, Dr. Richard Illgen of the University of Wisconsin, said he now realized that Dr. Dorr's technique was not the issue, but that Dr. Dorr had just started using the Zimmer hip before other surgeons."

45. Around this time, although Defendants still maintained that there were no issues with Durom Cup, other doctors began to stop implanting them. Even still, Defendants continued to market the Durom Cup to unsuspecting physicians and patients, selling hundreds of units between May 2008 and July 22, 2008.

46. Throughout 2008, while the Durom Cup was being implanted in patients across the United States and around the world, Defendants were accumulating mounting and overwhelming reports that the Durom Cups were failing at an alarming and undisclosed rate.

47. To date, Defendants have not issued a public recall of the Durom Cup and instead have described their action as only a "temporary suspension" of the device. Defendants have made the Durom Cup "unavailable for purchase in the United States," but have not voluntarily recalled the device.

48. Instead, Defendants transferred the defective design of the Durom Cup bone fixation surface to the MMC Cup, without modifications and without conducting animal, clinical

or other studies designed to test the effectiveness and safety of the resulting MMC Cup design and manufacture process.

49. Defendants failed to warn the medical community and the patients receiving the MMC Cup, including Plaintiff's physicians and Plaintiff, of the said defects in the design and manufacture of the MMC Cup. Instead, Defendants aggressively marketed the MMC Cup as safe and effective.

The Defects of the MMC Cup – A Defective Large Monoblock Device

50. Defendants knew or should have known that the Device, a large monoblock THA implant, is unreasonably difficult to implant and is susceptible to damage from ordinary surgical technique and wear and tear. Defendants knew or should have known that the unreasonable risk of edge loading and friction from the large diameter metal on metal prosthesis could contribute to enhanced levels of metal particles surrounding the site of the implant and could disseminate throughout the body.

51. Defendants failed to warn the medical community and the patients receiving the MMC Cup, including Plaintiff's physicians and Plaintiff, of the said defects in the design of the Device. Instead, Defendants aggressively marketed the MMC Cup and the Device as safe and effective, claiming that the large monoblock design delivers performance and safety benefits.

The Defects of the MMC Cup – Failure to Identify and Remedy the Defects in Design and Manufacture

52. During the time Defendants manufactured, marketed, distributed and sold the Device, including the MMC Cup, Defendants' inadequate manufacturing processes led to

material flaws in the manufacturing and quality, including design validation and quality, systems at their manufacturing facilities.

53. During the time Defendants manufactured, marketed, distributed and sold the Device, including the MMC Cup, Defendants failed in several ways, including, without limitation, by:

- a. Failing to conduct adequate mechanical testing on components; subassemblies and/or finished Device, including the MMC Cup;
- b. Failing to test an adequate number of sample devices on an ongoing basis;
- c. Failing to take adequate steps to specifically identify failure modes with clarity and suggest methods to monitor, avoid, and/or prevent further failures;
- d. Failing to identify and/or note the significance of any testing that resulted in failure of the Device, including the MMC Cup;
- e. Failing to take corrective actions to eliminate or minimize further failures of the Device, including the MMC Cup;
- f. Failing to adequately explain performance specifications for the components, subassemblies, and/or finished Device, including the MMC Cup;
- g. Failing to adequately explain or justify all test conditions and acceptance criteria for the Device, including the MMC Cup;
- h. Failing to perform adequate testing in an environment that adequately simulated in vivo conditions; and
- i. Failing to perform adequate quality assurance testing before and after sterilization.

54. Defendants failed to perform adequate testing of the Device and the MMC Cup, including its components and subassemblies, to ensure that the Device, including the MMC Cup, functioned properly during and after implantation.

55. As a result of these manufacturing and quality, including design validation and quality, control problems, the Device, including the MMC Cup, was inadequately and defectively designed and manufactured, in violation of the applicable governmental and/or industry standards.

The Defective Device and MMC Cup Caused Severe and Permanent Injuries to Plaintiff

56. Plaintiff has been significantly injured by, and continues to sustain injuries from, the Device, including the MMC Cup, that was implanted in his right hip.

57. Plaintiff's Device and MMC Cup have failed, causing significant injuries including, without limitation, severe pain, elevated cobalt and chromium ion levels, tissue and bone damage, and mechanical limitations to the hip function.

58. As a result of the failure of the Device and the MMC Cup, Plaintiff required a revision surgery to remove and replace the failed components.

59. Plaintiff continues to suffer from the injuries that the Device and the MMC Cup have caused. He is continuously in pain, experiences severe limitations in the function of the hip, and is subject to subluxations and dislocations of the affected hip. Plaintiff will likely require a re-revision surgery.

60. As a result of the failure of the Device and the MMC Cup, Plaintiff has been unable to continue his regular employment and other wage earning activities. He is currently unable to work due to the injuries to his right hip.

61. As a result of the failure of the Device and the MMC Cup, Plaintiff was caused to suffer continuing bodily injury, including a revision surgery, and was thus caused to sustain severe and permanent personal injuries, pain, suffering, and mental anguish.

62. As a result of the failure of the Device and the MMC Cup, Plaintiff was unable to continue his regular employment, and was thus caused to sustain loss of wages and wage earning capacity.

V. CLAIMS FOR RELIEF

FIRST CAUSE OF ACTION

STRICT LIABILITY: DESIGN DEFECT

63. Plaintiff incorporates by reference all preceding paragraphs as if fully set forth herein.

64. Defendants designed, manufactured, marketed, distributed, and sold and, at all times relevant hereto, were in the business of designing, manufacturing, marketing, and selling medical devices, including the Device and the MMC Cup received by Plaintiff, for implantation into consumers, such as Plaintiff, by physicians and surgeons in the United States, including in the State of North Dakota.

65. Defendants designed, manufactured, marketed, distributed, and sold the Device and the MMC Cup, including the device that was implanted in Plaintiff's right hip, in a defective condition unreasonably dangerous to the user or consumer.

66. The Device, including the MMC Cup, that was designed, manufactured, marketed, distributed, and sold by Defendants and implanted in Plaintiff was in a defective condition that was unreasonably dangerous to ordinary patients, such as Plaintiff, because it was dangerous to an extent beyond which would be contemplated by the ordinary and prudent buyer, consumer, or user of that product in that community considering the product's characteristics, propensities, risks, dangers, and uses, together with any actual knowledge, training, or experience possessed by that particular buyer, user, or consumer. Ordinary patients, and their physicians, including Plaintiff and his physicians, would not and could not have recognized or discovered the potential risks and side effects of the Device, including the MMC Cup, as set forth herein. Further, the risks and side effects of the Device outweigh the benefits, if any.

67. The design defects of the Device, including the MMC Cup, include but are not limited to the following:

a. The MMC Cup was defectively designed resulting in lack of fixation between the cup's outer surface and the pelvic bone:

i. The design of the Device, including (without limitation) the protruding fins on the outer surface of the MMC Cup and the requirement for under-reaming the natural pelvic bone during installation, made primary fixation unreasonably difficult to achieve during installation of the MMC Cup;

ii. The forged cobalt chrome alloy and the Ti-VPS coating of the MMC Cup are defective in design because they do not achieve adequate primary and secondary fixation (in-growth of the bone) due to reduced friction, and small size and inadequate structure of the pores;

b. the Device, including the MMC Cup, was defectively designed creating increased metal on metal wear between the femoral component and the acetabular component:

i. The Device, as a large monoblock THA implant, is unreasonably difficult to implant and is susceptible to damage from ordinary surgical technique and wear and tear; and

ii. The Device, as a large monoblock THA implant, presents an unreasonable risk of edge loading and friction that could contribute to enhanced levels of metal particles surrounding the site of the implant and throughout the body;

c. And, Defendants created defective surgical protocol for the Device, including the MMC Cup, which, among other things, creates a requisite implantation procedure for proper use of the device that is unreasonably difficult for most surgeons.

68. Defendants' Device, including the MMC Cup, components were expected to and did reach Plaintiff and his physicians without substantial change in their condition as designed, manufactured, distributed, and sold by Defendants. Additionally, Plaintiff's physicians used the Device, including the MMC Cup, in the manner in which the Device, including the MMC Cup, was intended to be used, making such use reasonably foreseeable to Defendants.

69. As a direct and proximate result of Defendants' manufacture, marketing, distribution, and sale of the Device, including the MMC Cup, Plaintiff was implanted with the same and has suffered serious physical injury, harm, damages and economic loss and will continue to suffer such harm, damages and economic loss in the future.

70. The defective design of the Device, including the MMC Cup, was a substantial factor in causing Plaintiff's injuries and damages, as described herein.

SECOND CAUSE OF ACTION

STRICT LIABILITY: FAILURE TO WARN

71. Plaintiff incorporates by reference all preceding paragraphs as if fully set forth herein.

72. Defendants designed, manufactured, marketed, distributed, and sold and, at all times relevant hereto, were in the business of designing, manufacturing, marketing, and selling medical devices, including the Device and the MMC Cup received by Plaintiff, for implantation into consumers, such as Plaintiff, by physicians and surgeons in the United States, including in the State of North Dakota.

73. The Device, including the MMC Cup, had potential risks and side effects that were known or knowable to Defendants by the use of scientific knowledge available at and after the time of manufacture, marketing, distribution and sale of the Device, including the MMC Cup, which was implanted in Plaintiff. Defendants knew or should have known of the defective condition, characteristics, and risks associated with said product, as previously set forth herein.

74. The Device, including the MMC Cup, that was designed, manufactured, marketed, distributed, and sold by Defendants and implanted in Plaintiff was in a defective condition that was unreasonably dangerous to ordinary patients, such as Plaintiff, because it was dangerous to an extent beyond which would be contemplated by the ordinary and prudent buyer, consumer, or user of that product in that community considering the product's characteristics, propensities, risks, dangers, and uses, together with any actual knowledge, training, or experience possessed by that particular buyer, user, or consumer. Ordinary patients, and their physicians, including Plaintiff and his physicians, would not and could not have recognized or

discovered the potential risks and side of effects of the Device, including the MMC Cup, as set forth herein. Further, the risks and side effects of the Device outweigh the benefits, if any.

75. The warnings and directions provided with the Device, including the MMC Cup, by Defendants failed to adequately warn of the potential risks and side effects of the Device, including the MMC Cup, and the dangerous propensities of said medical device, which risks were known or were reasonably scientifically knowable to Defendants.

76. The warning to Plaintiff and Plaintiff's implanting physicians about the dangers the Device, including the MMC Cup, posed to patients were inadequate. Examples of the inadequacy of Defendants' warnings include, but are not limited to, one or more of the following particulars:

a. The Device, including the MMC Cup, warnings were insufficient to alert Plaintiff and Plaintiff's physicians as to the risk, scope, duration and severity of adverse events and/or reactions associated with the Device, including the MMC Cup, subjecting Plaintiff to risks which exceeded the benefits of the Device, including the MMC Cup;

b. Defendants marketed and sold the Device, including the MMC Cup, using misleading material emphasizing the efficacy while downplaying the risks thereby making use of the Device, including the MMC Cup, more dangerous than the ordinary patient and physician would expect;

c. Defendants failed to disclose that the Device, including the MMC Cup, was inadequately tested;

d. Defendants failed to convey adequate post-marketing warnings regarding the risk, severity, scope and/or duration of the dangers posed by the Device, including the MMC Cup; and

e. Defendants failed to provide physicians, including Plaintiff's physicians, with information and instructions sufficient to avoid or mitigate the Device, including the MMC Cup's, dangers.

77. Specifically, Defendants failed to warn Plaintiff and his physicians that:

a. The design of the Device, including (without limitation) the protruding fins on the outer surface of the MMC Cup and the requirement for under-reaming the natural pelvic bone during installation, made primary fixation especially difficult to achieve during installation of the MMC Cup;

b. The forged cobalt chrome alloy and the Ti-VPS coating of the MMC Cup may not achieve adequate primary and secondary fixation (in-growth of the bone) due to reduced friction, and small size and inadequate structure of the pores;

c. Defendants did not conduct studies to test the effectiveness of the porous coating of the MMC Cup in achieving fixation through bone on-growth;

d. The Device, as a large monoblock THA implant, is difficult to implant and is susceptible to damage from ordinary surgical technique and wear and tear;

e. The Device, as a large monoblock THA implant, presents an increased risk of edge loading and friction that could contribute to enhanced levels of metal particles surrounding the site of the implant and throughout the body;

f. Defendants did not perform studies to test the effectiveness and safety of the Device, including of the MMC Cup; and

g. The above defects pose an increased risk of Device failure and a need for a surgery to remove and replace it.

78. Defendants' Device, including the MMC Cup, components were expected to and did reach Plaintiff and his physicians without substantial change in their condition as designed, manufactured, distributed, and sold by Defendants. Additionally, Plaintiff's physicians used the

Device, including the MMC Cup, in the manner in which the Device, including the MMC Cup, was intended to be used, making such use reasonably foreseeable to Defendants.

79. As a direct and proximate result of Defendants' manufacture, marketing, distribution, and sale of the Device, including the MMC Cup, Plaintiff was implanted with the same and has suffered serious physical injury, harm, damages and economic loss and will continue to suffer such harm, damages and economic loss in the future.

80. Defendants' lack of sufficient instructions or warnings prior to and after the date of Plaintiff's hip replacement surgery was a substantial factor in causing Plaintiff's injuries and damages, as described herein.

THIRD CAUSE OF ACTION

STRICT LIABILITY: MANUFACTURING DEFECT

81. Plaintiff incorporates by reference all preceding paragraphs as if fully set forth herein.

82. Defendants manufactured the Device that was implanted in Plaintiff's hip.

83. The Device that was implanted in Plaintiff's hip contained manufacturing defects in that it differed from the manufacturer's design or specifications, or from other typical units of the same product line.

84. The Device was manufactured in a manner that does not comply with the requirements of the Federal Food, Drug and Cosmetic Act, 21 U.S.C. § 321 *et seq.*, and the Medical Devices Amendment thereto (hereafter "FDCA").

85. The defective manufacture of the device made it unreasonably dangerous to ordinary patients, such as Plaintiff.

86. Plaintiff and Plaintiff's physicians did not know, and could not have reasonably discovered, that the Device was defectively manufactured.

87. Plaintiff's physicians employed the Device in the manner in which it was intended to be used, making such use reasonably foreseeable to Defendants.

88. As a direct and legal result of Defendants' defective manufacture of the Device, including the MMC Cup, Plaintiff suffered the injuries and damages, as described in this Complaint.

FOURTH CAUSE OF ACTION

NEGLIGENCE

89. Plaintiff incorporates by reference all preceding paragraphs as if fully set forth herein.

90. Defendants had a duty to exercise reasonable care in the design, formulation, testing, manufacture, labeling, marketing, sale and/or distribution of the Device, including the MMC Cup. In particular, they had a duty to assure that their products did not pose an unreasonable risk of bodily harm and adverse events. Defendants had a duty to ensure that the benefits of using the Device outweighed the risks.

91. Defendants failed to exercise reasonable care in the design, formulation, manufacture, sale, testing, marketing, or distribution of the Device, including the MMC Cup, in that they knew or should have known that the said devices could cause significant bodily harm

and were not safe for use. Defendants failed to ensure that the benefits of using the Device outweighed the risks.

92. Defendants failed to exercise ordinary care in the labeling of the Device, including the MMC Cup, and failed to issue to consumers and to their healthcare providers adequate warnings concerning the actual risks of serious bodily injury due to the Device, including the MMC Cup.

93. Despite the fact that Defendants knew or should have known that the Device, including the MMC Cup, posed a serious risk of bodily harm to consumers, Defendants unreasonably continued to manufacture and market said devices and failed to exercise reasonable care with respect to post-sale warnings and instructions for safe use.

94. At all relevant times, it was foreseeable to Defendants that consumers such as Plaintiff would suffer injury as a result of Defendants' failure to exercise ordinary care as described above.

95. As a direct and proximate result of Defendants' negligence, Plaintiff has suffered physical injuries, harm, damages and economic loss and will continue to suffer such harm, damages and economic loss in the future.

96. Defendants' negligence prior to and after the date of Plaintiff's hip replacement surgery was a substantial factor in causing Plaintiff's injuries and damages, as described herein.

FIFTH CAUSE OF ACTION

NEGLIGENCE: DESIGN DEFECT

97. Plaintiff incorporates by reference all preceding paragraphs as if fully set forth herein.

98. Defendants had a duty to exercise reasonable care in the design of the Device, including the MMC Cup. In particular, they had a duty to assure that their products did not pose an unreasonable risk of bodily harm and adverse events due to the design. Defendants had a duty to ensure that the benefits of using the Device outweighed the risks.

99. Defendants failed to exercise reasonable care in the design and formulation of the Device, including the MMC Cup, in that they knew or should have known that the Device, including the MMC Cup, could cause significant bodily harm and was not safe for use by consumers. Defendants failed to ensure that the benefits of using the Device outweighed the risks.

100. Defendants' negligence in designing the Device, including the MMC Cup, includes but is not limited to the following:

a. The MMC Cup was negligently designed resulting in lack of fixation between the cup's outer surface and the pelvic bone:

i. The design of the Device, including (without limitation) the protruding fins on the outer surface of the MMC Cup and the requirement for under-reaming the natural pelvic bone during installation, made primary fixation especially difficult to achieve during installation of the MMC Cup;

ii. The forged cobalt chrome alloy and the Ti-VPS coating of the MMC Cup are defective in design because they do not achieve adequate primary

and secondary fixation (in-growth of the bone) due to reduced friction, and small size and inadequate structure of the pores;

iii. Defendants did not conduct studies to test the effectiveness of the porous coating of the MMC Cup in achieving fixation through bone on-growth;

b. the Device, including the MMC Cup, was negligently designed creating increased metal on metal wear between the femoral component and the acetabular component:

i. The Device, as a large monoblock THA implant, is especially difficult to implant and is susceptible to damage from ordinary surgical technique and wear and tear; and

ii. The Device, as a large monoblock THA implant, presents an increased risk of edge loading and friction that could contribute to enhanced levels of metal particles surrounding the site of the implant and throughout the body;

c. And, Defendants created negligently designed surgical protocol for the Device, including the MMC Cup, which, among other things, creates a requisite implantation procedure for proper use of the device that is especially difficult for most surgeons.

101. At all relevant times, it was foreseeable to Defendants that patients such as Plaintiff would suffer injury as a result of the Defendants' failure to exercise ordinary care as described above.

102. As a direct and proximate result of Defendants' negligence, Plaintiff has suffered physical injuries, harm, damages and economic loss and will continue to suffer such harm, damages and economic loss in the future.

103. Defendants' negligence in designing the Device, including the MMC Cup, was prior to the date of Plaintiff's hip replacement surgery and was a substantial factor in causing Plaintiff's injuries and damages, as described herein.

SIXTH CAUSE OF ACTION

NEGLIGENCE: MANUFACTURING DEFECT

104. Plaintiff incorporates by reference all preceding paragraphs as if fully set forth herein.

105. Defendants manufactured the Device that was implanted in Plaintiff's hip.

106. Defendants had a duty to exercise reasonable care in the manufacture of the Device.

107. Defendants breached their duty to exercise reasonable care in the manufacture of the Device.

108. The Device that was implanted in Plaintiff's hip contained manufacturing defects in that it differed from the manufacturer's design or specifications, or from other typical units of the same product line.

109. The Device was manufactured in a manner that does not comply with the requirements of the Federal Food, Drug and Cosmetic Act, 21 U.S.C. § 321 *et seq.*, and the Medical Devices Amendment thereto (hereafter "FDCA").

110. Defendants knew or should have known of the said defects in the manufacture of the Device, but failed to remedy the said defects.

111. Plaintiff and Plaintiff's physicians did not know, and could not have reasonably discovered, that the Device was defectively manufactured.

112. Plaintiff's physicians employed the Device in the manner in which it was intended to be used, making such use reasonably foreseeable to Defendants.

113. As a direct and legal result of Defendants' defective manufacture of the Device, including the MMC Cup, Plaintiff suffered the injuries and damages, as described in this Complaint.

SEVENTH CAUSE OF ACTION

FRAUD AND DECEIT

114. Plaintiff incorporates by reference all preceding paragraphs as if fully set forth herein.

115. Defendants knowingly and intentionally made materially false and misleading representations to Plaintiff's healthcare providers and to the public, to the effect that the Device, including the MMC Cup, were safe for use and that their labeling, marketing and promotional materials fully described all known risks associated with the Device, including the MMC Cup.

116. Prior to the date when Plaintiff received the Device, in labeling materials intended for implanting surgeons and patients, and on their Internet website, Defendants made materially false and misleading representations to the effect that:

- a. The MMC Cup could be easily installed in a way that achieves reliable and reproducible primary fixation;
- b. The three pairs of fins provide additional primary fixation;
- c. The MMC Cup could be easily installed in a way that achieves reliable and reproducible secondary fixation (bone in-growth); and
- d. The porous coating on the outer surface of the MMC Cup achieves reliable and durable secondary fixation (bone in-growth).

117. Defendants made said materially false and misleading representations directly to Plaintiff's implanting surgeon through Defendants' sales representative(s) during sales meeting(s) prior to the date when Plaintiff received his defective Device.

118. Defendants made said materially false and misleading representations directly to Plaintiff's surgeon through Defendants' sales representative who was present in the operating room during the surgery in which Plaintiff received his defective Device.

119. Defendants' representations were in fact false. The Device was not safe for use and Defendants' labeling, marketing and promotional materials did not fully describe all known risks of the products. The MMC Cup is designed to be impacted into the pelvic bone to create primary fixation through press fit by under-reaming the pelvic bone to provide a seating space for the cup that is smaller than the outer dimension of the cup. However, the design of the cup includes protruding fins on the outer surface that make installation of the cup with the requisite press fit especially difficult. In addition, the structure and the size of the pores on the outer surface of the MMC Cup are not adequate for the bone to attach to, and to grow into, the surface of the cup. As a result, the MMC Cup is in fact difficult to implant in a way that achieves primary fixation, and subsequent bone in-growth and secondary fixation, to the pelvic bone.

120. Defendants made the said materially false and misleading representations without having a reasonable ground for believing that the representations were true.

121. Defendants had actual knowledge that the Device, including the MMC Cup, created an increased risk of serious bodily injury to consumers.

122. Defendants knew that the MMC Cup is in fact difficult to implant in a way that achieves primary fixation, and subsequent bone in-growth and secondary fixation, to the pelvic bone.

123. Defendants chose not to conduct animal, clinical or other studies designed to test the effectiveness and safety of the MMC Cup and the Device, including of the outer surface of the MMC Cup and its ability to achieve fixation to the pelvic bone.

124. Defendants knew that the Device, a large monoblock THA implant, is especially difficult to implant and is susceptible to damage from ordinary surgical technique and wear and tear. Defendants knew that the increased risk of edge loading and friction from the large diameter metal on metal prosthesis could contribute to enhanced levels of metal particles surrounding the site of the implant and could disseminate throughout the body. Defendants did not have a reasonable ground to believe that the Device did not have the said defects that are common to large monoblock THA implants.

125. Defendants knowingly and intentionally omitted this information from their labeling, marketing, and promotional materials and instead, labeled, promoted and marketed their products as safe for use in order to increase and sustain sales.

126. When Defendants made representations that the Device, including the MMC Cup, was safe for use, they knowingly and intentionally concealed and withheld from Plaintiff, his physicians and the public, the fact that the Device, including the MMC Cup, are not safe for use in consumers and posed an unacceptable high rate of failure and release of metal ion debris.

127. Defendants had a duty to disclose that the Device, including the MMC Cup, was not safe for use in patients and posed an unacceptable high rate of failure and release of metal ion debris.

128. Defendants had superior knowledge of the facts that were material to Plaintiff and his healthcare providers' decision to utilize the Device, including the MMC Cup.

129. Plaintiff and his healthcare providers reasonably and justifiably relied on the Defendants' representations that the Device, including the MMC Cup, was safe for use and that Defendants' labeling, marketing and promotional materials fully described all known risks associated with the products.

130. Plaintiff and his healthcare providers did not know, and could not have learned of the facts that the Defendants omitted and suppressed. The facts suppressed and concealed by the Defendants are material. Had Plaintiff and his healthcare providers known that the Device, including the MMC Cup, was not safe and posed an unacceptable high rate of failure and release of metal ion debris, Plaintiff would not have had the Device, including the MMC Cup, implanted.

131. As a direct and proximate result of Defendants' misrepresentations and concealment, Plaintiff was implanted with the Device, including the MMC Cup, and has suffered

serious physical injury, harm, damages and economic loss and will continue to suffer such harm, damages and economic loss in the future.

EIGHTH CAUSE OF ACTION

FRAUD AND DECEIT: CONCEALMENT, SUPPRESSION OR OMISSION OF MATERIAL FACTS

132. Plaintiff incorporates by reference all preceding paragraphs as if fully set forth herein.

133. Defendants omitted, suppressed, or concealed material facts concerning the dangers and risks associated with the use of the Device, including the MMC Cup, including but not limited to the following:

- a. The protruding fins on the outer surface of the MMC Cup make installation of the cup with the requisite press fit especially difficult;
- b. The structure and the size of the pores on the outer surface of the MMC Cup are not adequate for the bone to attach to, and to grow into, the surface of the cup;
- c. As a result, the MMC Cup is difficult to implant in a way that achieves primary fixation, and subsequent bone in-growth and secondary fixation, to the pelvic bone;
- d. The Device, a large monoblock THA implant, is unreasonably difficult to implant and is susceptible to damage from ordinary surgical technique and wear and tear.
- e. The increased risk of edge loading and friction from the large diameter metal on metal prosthesis could contribute to enhanced levels of metal particles surrounding the site of the implant and could disseminate throughout the body;

f. Defendants did not conduct studies to test the efficacy and safety of the MMC Cup and the Device, including of the outer surface of the MMC Cup and its ability to achieve fixation to the pelvic bone;

g. As a result of the above design limitations, the Device posed an increased risk of failure and the need for a surgery to remove and replace it.

134. Rather, Defendants purposely downplayed and understated the serious nature of the risks associated with use of the Device, including the MMC Cup, in order to increase and sustain sales.

135. Defendants had a duty to disclose that the Device, including the MMC Cup, was not safe for use in patients and posed an unacceptable high rate of failure and release of metal ion debris.

136. The facts that Defendants omitted, suppressed, and concealed, as set forth above, were material to the consumers and their physicians, and, in particular, to Plaintiff's and his physicians' decision to implant the Device, including the MMC Cup, in Plaintiff.

137. Defendants had superior knowledge of the facts that they omitted, suppressed, and concealed.

138. Defendants omitted, suppressed, and concealed material facts, as set forth above, while making false, misleading, and partial representations regarding the Device, including the MMC Cup.

139. Prior to the date when Plaintiff received the Device, in labeling materials intended for implanting surgeons and patients, and on their Internet website, Defendants made materially false, misleading and partial representations to the effect that:

- a. The MMC Cup could be easily installed in a way that achieves reliable and reproducible primary fixation;
- b. The three pairs of fins provide additional primary fixation;
- c. The MMC Cup could be easily installed in a way that achieves reliable and reproducible secondary fixation (bone in-growth); and
- d. The porous coating on the outer surface of the MMC Cup achieves reliable and durable secondary fixation (bone in-growth).

140. Defendants made said materially false, misleading and partial representations (while withholding material facts) directly to Plaintiff's implanting surgeon through Defendants' sales representative(s) during sales meeting(s) prior to the date when Plaintiff received his defective Device.

141. Defendants made said materially false, misleading and partial representations (while withholding material facts) directly to Plaintiff's surgeon through Defendants' sales representative who was present in the operating room during the surgery in which Plaintiff received his defective Device.

142. Defendants actively concealed material facts, as set forth above, by continuing to market and sell the Device, including the MMC Cup, despite their knowledge that the Device, including the MMC Cup, are defective and pose serious risk of injury. Instead, they promoted the Device as providing a purported and exaggerated benefit of stability due to large size.

143. Plaintiff and his physicians did not know, and could not have learned of the facts that the Defendants omitted and suppressed.

144. Defendants' omission, suppression, and concealment of material facts, as set forth above, induced reasonable and justifiable reliance by Plaintiff and his healthcare providers in that Plaintiff and his healthcare providers made the decision to use the Device, including the MMC Cup, without the knowledge of the said material facts. Instead, Plaintiff and his healthcare providers reasonably and justifiably relied on the Defendants' representations that the Device, including the MMC Cup, was safe for use and that Defendants' labeling, marketing and promotional materials fully described all known risks associated with the products. Had Plaintiff and his healthcare providers known that the Device, including the MMC Cup, was not safe and posed an unacceptable high rate of failure and release of metal ion debris, Plaintiff would not have had the Device, including the MMC Cup, implanted.

145. As a direct and proximate result of Defendants' concealment of material facts, Plaintiff was implanted with the Device, including the MMC Cup, and has suffered physical injury, harm, damages and economic loss and will continue to suffer such harm, damages and economic loss in the future.

NINTH CAUSE OF ACTION

NEGLIGENT MISREPRESENTATION

146. Plaintiff incorporates by reference all preceding paragraphs as if fully set forth herein.

147. Defendants had a duty of reasonable care in supplying the public and Plaintiff's healthcare providers with true and complete information with respect to the safety and efficacy of the Device, including the MMC Cup.

148. Defendants supplied the public and Plaintiff's healthcare providers with materially false and incomplete information with respect to the safety of the Device, including the MMC Cup.

149. The false information supplied by Defendants was that the Device, including the MMC Cup, was safe and did not pose an unacceptable high rate of failure or release high levels of metal ion debris.

150. Prior to the date when Plaintiff received the Device, in labeling materials intended for implanting surgeons and patients, and on their Internet website, Defendants made materially false and misleading representations to the effect that:

- a. The MMC Cup could be easily installed in a way that achieves reliable and reproducible primary fixation;
- b. The three pairs of fins provide additional primary fixation;
- c. The MMC Cup could be easily installed in a way that achieves reliable and reproducible secondary fixation (bone in-growth); and
- d. The porous coating on the outer surface of the MMC Cup achieves reliable and durable secondary fixation (bone in-growth).

151. Defendants made said materially false and misleading representations directly to Plaintiff's implanting surgeon through Defendants' sales representative(s) during sales meeting(s) prior to the date when Plaintiff received his defective Device.

152. Defendants made said materially false and misleading representations directly to Plaintiff's surgeon through Defendants' sales representative who was present in the operating room during the surgery in which Plaintiff received his defective Device.

153. In supplying this false information, Defendants failed to exercise reasonable care.

154. The false information communicated by Defendants to Plaintiff and his healthcare providers was material and Plaintiff and his healthcare providers justifiably relied in good faith on the information to his detriment.

155. As a direct and proximate result of Defendants' misrepresentations, Plaintiff was implanted with the Device, including the MMC Cup, and has suffered physical injury, harm, damages and economic loss and will continue to suffer such harm, damages and economic loss in the future.

TENTH CAUSE OF ACTION

BREACH OF EXPRESS WARRANTY

156. Plaintiff incorporates by reference and realleges each paragraph set forth above.

157. At all times herein mentioned, Defendants expressly warranted to Plaintiff and Plaintiff's physicians, by and through statements made by Defendants, or their authorized agents or sales representatives, orally and in publications, package inserts and other written materials intended for physicians, medical patients and the general public, that the aforementioned Device, including the MMC Cup, was safe, effective, fit and proper for its intended use.

158. In utilizing the aforementioned Device, including the MMC Cup, Plaintiff and Plaintiff's physicians relied on the skill, judgment, representations and foregoing express warranties of Defendants.

159. Said warranties and representations were false in that the aforementioned Device, including the MMC Cup, was not safe and was unfit for the uses for which it was intended.

160. As a result of the foregoing breach of express warranties by Defendants, Plaintiff suffered injuries and damages as alleged herein.

ELEVENTH CAUSE OF ACTION

BREACH OF IMPLIED WARRANTIES

161. Plaintiff incorporates by reference and realleges each paragraph set forth above.

162.- Prior to the time that the Device, including the MMC Cup, was used by Plaintiff, Defendants impliedly warranted to Plaintiff and Plaintiff's physicians that the Device, including the MMC Cup, was of merchantable quality and safe and fit for the use for which it was intended.

163. Plaintiff and Plaintiff's physician were and are unskilled in the research, design and manufacture of the Device, including the MMC Cup, and they reasonably relied entirely on the skill, judgment and implied warranty of Defendants in using the Device, including the MMC Cup.

164. The Device, including the MMC Cup, was neither safe for its intended use nor of merchantable quality, as warranted by Defendants, in that it had dangerous propensities when put to its intended use and would cause severe injuries to the user.

165. Defendants, by selling, delivering and/or distributing the defective Device, including the MMC Cup, to Plaintiff breached the implied warranty of merchantability and fitness and caused Plaintiff to suffer severe pain and emotional distress, incur medical expenses and incur a loss of earning capacity.

166. As a result of the aforementioned breach of implied warranties by Defendants, Plaintiff suffered injuries and damages as alleged herein.

TWELFTH CAUSE OF ACTION

VIOLATION OF CONSUMER PROTECTION LAW

167. Plaintiff hereby incorporates by reference all preceding paragraphs as if fully set forth herein.

168. Plaintiff was a consumer who paid for and underwent an implantation of the Device.

169. Defendants practiced unfair and deceptive acts as set forth above in marketing this product as safe and effective when in fact it was defective and unreasonably dangerous for implantation in the human body.

170. Plaintiff suffered injury to his person and property by expending funds for the purchase of this product and incurring ascertainable economic loss as a result of the implantation of the product.

171. This loss was caused as a result of the misrepresentation of Defendants to Plaintiff and his surgeon and hospital.

172. Plaintiff and his surgeon and hospital relied on these misrepresentations in choosing to implant an MMC Cup in Plaintiff.

173. As a result, Plaintiff suffered injuries and damages.

174. Pursuant to the applicable law, including (without limitation) N.D. Cent. Code, § 51-15-01 *et seq.*, Plaintiff seeks actual damages, treble damages, and the cost of suit, including reasonable attorneys' fees.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff prays for judgment against Defendants as follows:

1. Economic and non-economic damages in an amount in excess of \$75,000 as provided by law and to be supported by the evidence at trial;
2. For compensatory damages according to proof;
3. For treble damages;
4. For an award of attorneys' fees and costs;
5. For prejudgment interest and the costs of suit; and
6. For such other and further relief as this Court may deem just and proper.

DEMAND FOR JURY TRIAL

Plaintiff demand a jury trial on all claims so triable in this civil action, as provided by Rule 38 of the Federal Rules of Civil Procedure.

Dated: October 6, 2016

Respectfully Submitted,

/s/ Jeffrey S. Weikum

By:

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